Summary of Community Networking Questions
Held at CVB Public Meeting

Session 1: Wednesday September 23, 1998

Question 1: How confident are you in the safety of veterinary biological products?

There appears to be consensus among the groups that veterinary biological products are safe. Twenty-one of the 28 groups reporting, explicitly stated they had a high level of confidence around the safety of veterinary terinary biological products. One group made it clear that while they had great confidence in the safety of vet diagnostic kit, they did not have as high a level of confidence in vaccines. There were three groups that did not have clear consensus around safety, while in four other groups, their position around safety was unclear.

Other themes that emerged from the notes around safety included the following:

--Safety could be improved upon if more training was provided to users of the products, veterinarians or others. Off-label use is an issue which impacts the safety of products.

--The definition of safety has changed. Consumers have a more rigorous (narrow) definition of safety. Shifted from: A product is safe if it causes no death in the animal, to: A product is safe if it causes no adverse reactions in the animal.

--Current testing on single species only--mice or rats for example--may not provide adequate information around the safety of various products. Further analysis on a broader genetic base may be needed.

Question 2: How confident are you in the efficacy of veterinary biological products?

There appeared to be no definitive position around the efficacy of biological products. Six of the 29 groups stated that they had a fairly high level of confidence in the efficacy of these products, although some of them qualified their statements that efficacy was high "as per the label claim", or "as per the 9 CFR."

A handful of groups indicated that they thought the efficacy of veterinary biological products had improved dramatically over time, in other words, that newer products were probably more efficacious than older products. Several issues, however, contribute to the greater variability of opinion around efficacy. They are:

--Off-label use of veterinary biological products can have a tremendous impact on a product's efficacy. Because off-label use is very great, efficacy will always be a greater concern than safety. Better education of users is, perhaps, the only alternative to this problem, but it is difficult.

--There are also some very unrealistic expectations held by various user groups around efficacy. For example, pet owners generally have a higher set of expectations for efficacy than animal

producers (farmers/ranchers) do. Also, there are different expectations held by individuals around different products. For one type of product a veterinarian may have a certain expectation about efficacy, but for a different type of product, the same veterinarian may have a second level of expectation.

--Twelve of the 29 groups stated that the current way products are tested for efficacy may often yield unrealistic results. Using field trials would more closely resemble real world environments and factors. The current system using standard challenge models doesn't always provide the most reliable, valid efficacy results. While there was not consensus from meeting participants about whether manufacturers would be in favor of using more field trials (due to expenses, etc.), it was acknowledged that there is a disparity between real-world efficacy and the current testing requirements for making efficacy claims.

--There also is concern over duration of immunity claims on various manufacturers labels. People generally agreed, when the issue was raised, that more data needs to be collected on these claims, and that further guidance as to labeling requirements could be helpful. Some groups stated that USDA should consider creating some ***(more/clearer?)*** standards around this topic.

3. Are veterinary biological products readily available to the veterinarians and/or animal owners who need them?

Twenty-one of the 29 groups said that most products are widely available for users. In fact, several of the groups believed that the high degree of availability may ultimately contribute to misuse or off-label use of a variety of products. Seven groups did acknowledge, however, that many niche markets were under served, mostly because of the economics of production. Relatively low demand for a product influenced a firm's willingness to supply it.

There were several groups that expressed concern over new products taking more time to move through the regulatory process. Sometimes they believed that new science or methods were not always "compatible" with the regulatory process. That is, some other types of testing methods/models are difficult to get through the licensing process because the process is geared for more traditional science. (vaccination/challenge studies vs. other models)

Several groups did, however, indicate that they would like to see some type of fast-track regulatory process developed for "high-need" products or even products that were only slightly altered or improved.

4. As you reflect upon the CVB testing/inspection/licensing process, which aspects work well in your opinion? Which aspects need improvement?

The 29 groups offered comments in two ways. Most of the groups gave specific feedback on each of the three arms of CVB, providing positive feedback and suggestions for improvements. Other groups, however, gave a general response for CVB overall.

Feedback for CVB overall can be described in the following way:

First, CVB was commended by several groups to be open to comments, suggestions, and questions. Many of the groups stated that processes used like this community networking session were typical of the way CVB approaches the industry. There was appreciation expressed for that openness. Also, it was noted, that despite any criticism, CVB is good at meeting emergency needs for both the specific firms and the animal industry overall. Firms acknowledged that when it came to high priority items, they could always get CVB's attention. The other comment made several times was that the move of all three sections to Ames, IA was a positive thing. While only three or four groups stated it explicitly, there were no negative comments made about the move. In fact, in some of the feedback about the specific CVB sections, references were made to improvements in response time on certain issues since the move.

Suggestions for CVB as a whole included better communication between the three groups, developing a better regulatory process for new products that use new scientific methods or models, and a general concern about dwindling financial and human resources. User fees were even mentioned by some groups as a possible option to help CVB deal with their shrinking financial resources. There is a perception throughout these groups that the latest scientific technology is slipping away from CVB because of this situation.

Feedback for the specific groups within CVB can be described as follows:

CVB-LPD: Consistency of reviews was the biggest concern among the groups. Twelve of the 29 groups expressed a need for greater consistency among reviewers, and also among firms. Several groups mentioned that small and large firms at times, seem to be held to varying standards, which should be addressed, or at least explained. The second concern was that the review process is taking too long. Again, 12 groups expressed this concern. It was noted that review time has improved since the move to Ames, IA was completed, but there is still a need for greater timeliness. Some suggestions around this included hiring additional personnel, possibly even some paraprofessionals to handle some of the review work, and getting outside consultants from industry to help develop regulatory processes for reviewing new types of products that use new science. Positive feedback about the LPD group included that the reviewers are generally accessible and open to suggestions.

CVB-IC: Again, consistency was the most common theme that emerged for this group, although fewer groups raised it as a concern. There was also a suggestion made that IC should work more closely with firms when complaints or adverse reports come in. In general, however, the IC groups is seen as flexible, very well-organized, and usually looking to help firms, not hurt them, when conducting inspections.

CVB-Lab: Although there were several suggestions made, there appeared to be no distinct, underlying, concerns raised for the lab. Two or three of the groups did indicate they felt check-testing yielded very little. A few groups expressed concern over some of the Lab's testing systems, noting that sometimes CVB's testing methods did not match up with the industry's latest testing methods. Usually this comment was followed by a comment that CVB is lagging behind the industry in science and technology, due to dwindling resources. Three groups mentioned that it would be useful to standardize tests and reagents, and there were a couple of groups suggesting

that new references need to be made. Finally, several of the groups did express their appreciation for the high level of accessibility of Lab personnel and other resources.

Session 2: Thursday September 24, 1998

Given the wide array of variables that impact the veterinary biologics industry...where do you believe the Center for Veterinary Biologics should focus its primary human and financial resources over the next 5 years? 10 years?

There were many ideas mentioned in these discussion groups. The difficulty in analyzing these comments is that while some of the groups indicated which items they felt were high, medium, and low priority for the Center, most groups did not. It is probably appropriate to assume, then, that all the items listed for groups not making this distinction are high priority items. In addition, most groups did not distinguish between 5 year and 10 year goals and priorities. Therefore it is more difficult to determine what the groups viewed as longer rather than shorter term goals. Despite these problems, there were a few items raised as priorities in a fairly significant number of groups.

International harmonization was mentioned most frequently as a priority for CVB. About 14 groups mentioned it as either a "high" or "medium" priority for the Center. There was a sentiment, however, that a lot of time and resources have already been spent on this effort, with little tangible progress to the regulated industry. One group said that although it was a priority, CVB should decide to either put significant resources in it or stop investing in it all together. Other groups expressed the idea that while harmonization may not be feasible, mutual recognition may be possible. There was urging to further explore this option.

At this point, there was a cluster of items mentioned by equal numbers of various groups (about 6 groups each).

--First thing was a concern that CVB increase its capacity for handling greater volumes of electronic communication with the biologics firms. Many groups expressed concern with the heavy reliance on paper documents, mail couriers, etc.;

--Second, there is a desire for CVB to **(*help--or be responsible for?)*** standardize reagent production and references;

--Next, CVB should cease check testing and spend these resources on reviewing new product submissions for firms;

--Streamline regulatory requirements, including modifying and updating the CFR by eliminating any obsolete regulations or guidelines;

--A general sentiment that CVB overall needs to update and increase its technological capacities. Some of the comments were a blend of comments over better electronic communication with firms and general concern over technological lags between the industry and the Center as a whole.